510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K071839 .

1. Submitter's Identification:

Reichert, Inc.
c/o Sandra Brown
Quality Regulatory Affairs Manager
3362 Walden Avenue
Depew, NY 14043
Tel: (716) 686-4599

Date Summary Prepared: January 24, 2008

2. Name of the Device: SOCT Copernicus

3. Common or Usual Name: Optical Coherence Tomographer (OCT)

4. Predicate Device Information:

- **Trade Name**: STRATUS OCT
- **510(k) Number**: K030433
- **Common Name**: Optical Coherence Tomographer (OCT)
- **Classification Name**: Ophthalmoscope, AC-powered
- **Classification**: Class II
- **Classification Panel**: 86
- **Product Code:** HLI
- **Regulation Number:** 886.1570

5. SOCT Copernicus Device Description:

The SOCT Copernicus is an AC-powered device containing illumination and viewing optics intended to examine the retina of the eye.

SOCT Copernicus Intended Use:

The SOCT Copernicus is an optical coherence tomography system indicated for the in-vivo imaging and measurement of the retina as an aid in the diagnosis and management of retinal diseases.

6. Technological Characteristics:

The Reichert SOCT Copernicus and the predicate device have similar technological characteristics. Both devices utilize Optical Coherence Tomography, which relies upon interferometry of superluminescent diode light, reflected from the fundus of the eye, to produce a cross-sectional image of the retina. Both devices have similar hardware components. Like the predicate device, the SOCT Copernicus consists of a main unit, which houses the optical system used for imaging the retina, the light source, and a power supply. In addition, both systems utilize a chin rest/forehead rest assembly for patient interface and a computer with software for data analysis / image processing.

A brief summary of major technological characteristics for both devices is presented below:

	Factor	Subject Device Reichert "SOCT Copernicus"	Predicate Device Carl Zeiss "STRATUS OCT"
1	Method of Operation	Optical Coherence Tomography: Spectral / Fourier Domain	Optical Coherence Tomography: Time Domain
2	Exposure Parameters	750 µW at the cornea	750 µW at the cornea
3	Light Source	SLED. scan beam wavelength is 840 nm.	SLED. scan beam wavelength is 820 nm.
4	OCT Image	25,000 A-scan/second	400 A-scan/second
5	Depth Resolution (in tissue)	6 µm	10 µm
6	Transverse Resolution	12 µm 18 µm typical	20 µm

7. **Discussion of Clinical Tests Performed:**

SOCT Copernicus Precision Test (Repeatability and Reproducibility)

A structured study was conducted with 3 operators (unaware of patient pathology) and 2 devices to determine repeatability and reproducibility precision values for the SOCT Copernicus. The test population consisted of 10 normal eyes (with a wide range of media opacity and other parameters affecting image quality) and 10 pathological eyes including eyes with parameters affecting image quality such as diabetic macular edema, wet AMD, dry AMD, cystoid macular edema, vitreous hemorrhage, epiretinal membrane and/or vitromacular traction, and macular holes.

Statistical analysis of the study data showed good agreement across devices and operators.

SOCT Copernicus Clinical Comparison

A prospective case series comparing the Carl Zeiss Meditec Stratus™ Time Domain Optical Coherence Tomography (TDOCT) to the Reichert Copernicus™ Spectral Domain OCT (SDOCT) was performed at the Cleveland Clinic Cole Eye Institute.

A total of 27 eyes from 21 patients with a variety of vitreo-retinal disorders, including five normal eyes, were scanned with both machines and analyzed. All scans were analyzed to obtain values from nine fields: central subfield, temporal inner retina, superior inner retina, nasal inner retina, inferior inner retina, temporal outer retina, superior outer retina, nasal outer retina, and inferior outer retina.

Based on the results of the statistical analysis, no medically significant difference seems to exist between the measurements made by the two devices.

9. **Conclusions:**

- The SOCT Copernicus and Stratus OCT are both intended for in-vivo imaging and measurement of the retina as an aid in the diagnosis and management of retinal diseases.

- The SOCT Copernicus and Stratus OCT use similar technology with the exception that SOCT Copernicus utilizes Spectral Domain technology whereas the Stratus OCT uses Time Domain technology. Spectral Domain technology results in higher resolution retinal images. In addition, the SOCT Copernicus PC software is different from the Stratus OCT, but has been completely tested and validated.

- The devices are substantially equivalent based on the precision, repeatability and clinical testing described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2008

Reichert, Inc.
c/o Ms. Sandra Brown
Quality/Regulatory Affairs Manager
3362 Walden Avenue
Depew, NY 14043

Re: K071839
Trade/Device Name: SOCT Copernicus Spectral Optical Coherence Tomographer
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: Undated
Received: February 15, 2008

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071839

Device Name: Reichert SOCT Copernicus Spectral Optical Coherence Tomographer

Indications For Use:

An optical coherence tomography system indicated for the in vivo imaging and measurement of the retina as an aid in the diagnosis and management of retinal diseases.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K071839

Prescription Use ✓
(Per 21 CFR 801.109)